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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/668,629 | 09/23/2003 | James P. Delaney | 10123/03501 | 2181 |

7590 01/21/2010
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| EXAMINER |
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REYNOLDS, STEVEN ALAN

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| ART UNIT | PAPER NUMBER |
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3728

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| MAIL DATE | DELIVERY MODE |
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01/21/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/668,629 | Applicant(s) DELANEY ET AL. | |
| | Examiner STEVEN REYNOLDS | Art Unit 3728 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-28 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6 and 9-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the reply filed on 12/17/2009, wherein claims 1, 4, 15, 21, 26, 27 and 28 were amended.

Claim Objections

2. Claims 1, 5, 9, 11-13, 15, 18, 20, 21, 26, 27 and 28 are objected to because of the following informalities: the term "hydration opening" should be changed to "hydration port" to properly correspond to the present amendments. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 14, it is not clear how the ratio of fluid flow at the first end to fluid flow at the second end can be one to one if claim 12 recites that the amount of flow toward the first end is different than the amount of flow directed toward the second end.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1, 5, 9-15 and 18-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Addy et al. (US 6,594,971).

Regarding claim 1 and 5, Addy discloses a protective package (See Fig. 6) for a catheter, comprising: a protective sheath including a lumen (70) sized to removably protect a catheter (24/26/28) before use, the sheath having a length corresponding to a length of a catheter to be received therein and an inner diameter slightly greater than an outer diameter of a catheter to be received therein, a first end of the sheath being adapted to receive a distal end (26) of a catheter to be received therein and a second end of the sheath being adapted to receive a proximal end (28) of a catheter to be received therein; and a hydration port/adaptor (78) capable of receiving a fluid delivery device into the lumen disposed between the first and second ends of the sheath so that a desired proportion of a flushing fluid may be introduced into the lumen near a middle of the sheath (equidistant from the first and second ends) and so that a desired proportion of flow thereinto can be directed toward the first and second ends of the sheath with a first flow stream extending from the hydration port to the distal end of the catheter and a second flow stream extending from the hydration port to the proximal end of the catheter.

Regarding claims 9, 10 and 12-14, Addy discloses the hydration port is adapted to divide a flow of liquid thereinto to achieve a desired ratio of fluid flow at the first end to fluid flow at the second end (the ratio of flow at the first end to the second end can be

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one to one or any desired ratio depending on the orientation of the package and/or the orientation of the fluid flushing device when the fluid is introduced).

Regarding claim 15, Addy discloses a catheter kit (See Fig. 6) comprising: a catheter (24) having a distal end (26) and a proximal end (28); and a catheter packaging comprising: a tubular enclosure (70) removably protecting the catheter before use, the tubular enclosure having a length corresponding to a length of the catheter and an inner diameter defining a lumen that is slightly greater than an outer diameter of the catheter; a first end of the tubular enclosure being adapted to receive the distal end and, a second end of the tubular enclosure being adapted to receive the proximal end of the catheter; and a hydration port (78) capable of receiving a fluid delivery device and extending into the lumen between the first and second ends of the tubular enclosure, the hydration port being positioned so that a desired proportion of flow of a flushing fluid can be introduced into the lumen and enters the lumen near a middle of the enclosure and is directed toward the first and second ends of the enclosure such that a first flow stream extends from the hydration port to the distal end of the catheter and a second flow stream extends from the hydration port to the proximal end of the catheter (any amount of fluid can be introduced/directed toward any portion of the packaging depending on the orientation of the package when the fluid is introduced).

Regarding 18-20, Addy discloses a hydrating fluid introduced into the tubular enclosure via the hydration port can be divided such that the proximal end and the distal end of the catheter are substantially-equally hydrated; the catheter can be considered a micro-catheter ("micro" is a relative term, the catheter of Addy can be considered to be

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micro with respect to a larger catheter) with a shaped tip (the term "shaped" is a broad term that can encompass a tip having any shape); and the port is substantially equidistant between the first and second ends.

Regarding claim 21, Addy discloses a protective package (See Fig. 6) for removably receiving an elongated medical device, comprising: a protective sheath including a lumen (70) sized to tightly fit a body of the elongated medical device (24) to be removably received therein to protect the elongated device before use, the sheath having a length corresponding to a length of the medical device and an inner diameter slightly greater than an outer diameter of the elongated device, a first end of the sheath being adapted to receive a distal end (at 26) of the elongated medical device and a second end of the sheath being adapted to receive a proximal end (at 28) of the elongated medical device and a hydration port (78) capable of receiving a fluid delivery device into the lumen near a middle of the sheath so that a desired proportion of a flushing fluid that may be supplied to the sheath via the hydration port can be directed toward the first and second ends of the sheath with a first flow stream extending from the hydration port to the distal end of the elongated device and a second flow stream extending from the hydration port to the proximal end of the elongated device.

Regarding claims 22-25, Addy discloses a portion of the lumen for receiving a distal end of the elongated medical device is curved in a manner complimenting a preformed curve of the distal end of the medical device (See Fig. 6); a first portion of the lumen for receiving a distal end of the elongated medical device has a first diameter (diameter near the end portion of 72) different than a second diameter (diameter near

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the top portion of 71 near element 24 in Fig. 6) of a second portion of the lumen for receiving a proximal end of the body of the elongated medical device, the differences in the diameters of the first and second portions corresponding to differences in diameter between the proximal and distal portions of the elongated medical device; the first diameter is less than the second diameter; and a reinforced end (portion of the package where adhesive flap 80 overlaps the sheath is considered a reinforced portion as it comprises more than one layer of material) of a first portion of the lumen for receiving a distal end of the elongated medical device capable of protecting the distal end of the elongated medical device.

Regarding claim 26, Addy discloses a protective package for removably receiving-an elongated medical device, comprising: a protective sheath including a lumen (70) sized to tightly fit a body of the elongated medical device to be received therein, the sheath removably protecting the elongated medical device before use, a first end of the sheath being adapted to receive a distal end of the elongated medical device and a second end of the sheath being adapted to receive a proximal end of the elongated medical device, a length of the sheath corresponding to a length of the elongated medical device and an inner diameter of the lumen being slightly greater than an outer diameter of the elongated medical device; and a hydration port (78) capable of receiving a fluid delivery device into the lumen between the first and second ends of the sheath, the hydration port being positioned so that a flushing fluid that may be supplied to the hydration port is supplied to the lumen near a middle of the sheath with a desired proportion of flow thereinto being directed toward the first and second ends of the

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sheath such that a first flow stream extends from the hydration port to the distal end of the elongated medical device and a second flow stream extends from the hydration port to the proximal end of the elongated medical device.

Regarding claim 27, Addy discloses a packaging method for a catheter comprising: providing a catheter having a distal end and a proximal end; providing a shipping packaging in the form of a tubular enclosure (70) having a length corresponding to a length of the catheter and an inner diameter defining a lumen that is slightly greater than an outer diameter of the catheter, a first end of the tubular enclosure being adapted to receive the distal end; a second end of the tubular enclosure being adapted to receive the proximal end of the catheter; providing the tubular enclosure with a hydration port (78) capable of receiving a fluid delivery device extending into the lumen between the first and second ends of the tubular enclosure, the hydration port being positioned so that a desired proportion of a flow of flushing fluid that may be introduced into the lumen via the hydration opening can enter the lumen near the middle of the catheter and can be directed toward the first and second ends of the enclosure such that a first flow stream extends from the hydration port to the distal end of the catheter and a second flow stream extends from the hydration port to the proximal end of the catheter; and removably inserting the catheter into the lumen of the tubular enclosure.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 2, 3, 6, 16, 17 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Addy et al. (US 6,594,971).

Regarding claims 2 and 17, as described above, Addy discloses the claimed invention except for the specific orientation of the sheath. However, it would have been obvious to one of ordinary skill in the art to have looped the ends of 26 and 28 inwardly toward one another to form a hoop in order to give the device a more compact orientation for shipping.

Regarding claims 3, 6, 16 and 28, as described above, Addy discloses the claimed invention except for the protective assembly. However, because Applicant has not traversed Examiner's assertion of Official Notice, the fact that it is well known to place flexible packaging devices within rigid shipping boxes is taken to be admitted prior

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art. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made in view of Applicants admitted prior art to provide a rigid outer box to the device of Addy to protect the device during shipping. This outer box would protect both the distal and proximal ends of the device and help maintain the shape of the ends from being deformed from the outside environment.

Allowable Subject Matter

9. Claim 4 is allowed.

Response to Arguments

10. Applicant's arguments filed 12/17/2009 have been fully considered but they are not persuasive. Regarding the 35 U.S.C. 112, second paragraph rejection of claim 14: the amendment to claim 13 does not overcome the rejection, claim 12 still requires the amount of flow at the first end to be different than the amount of flow at the second end.

Applicant argues that Addy does not teach a port. Contrary to Applicant's argument: the term "port" can be defined as "an opening, as in a cylinder or valve face, for the passage of steam or fluid". [The American Heritage Dictionary of the English Language, Fourth Edition, 2009]. Therefore, the opening (78) of Addy can be considered a port; the port 78 is fully capable of receiving a fluid delivery device.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEVEN REYNOLDS whose telephone number is (571)272-9959. The examiner can normally be reached on Monday-Friday 9:30am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571)272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. R./
Examiner, Art Unit 3728

/Mickey Yu/
Supervisory Patent Examiner, Art
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